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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,678	09/28/2001	Suzanne De La Monte	0609.4370002	3649

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EXAMINER
WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
1635	18

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/964,678	Applicant(s) MONTE ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *7-9,14-16 and 35-40*.

   Claim(s) withdrawn from consideration: *None*.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The rejection under 112 first paragraph written description for claims 7, 9, 14, 16, and 35-36 remain for the reasons of record and the applicants have not provided new arguments that would require further explanation. The rejection for claims 7-9,14-16,35-40 under 112 first paragraph enablement for the reasons of record and applicants have not provided new arguments that would require further explanation.

With respect to Exhibits A-E, the argument is moot because the material and methods used in the Exhibits are not the same as the materials and methods used in the specification. In addition, the art of record teaches, "We were unable to investigate whether over-expression of AD7c-NTP might contribute to AD neurodegeneration using standard transfected cells because of the depletion of cell in culture (De La Monte et al., Journal of Neuropathology an Experimental Neurology, Vol. 60, pages 195-207, 2001). If over-expression of AD7c-NTP resulted in cell death and depletion of cells in cultures, then one skilled in the art would conclude that overexpression of AD7c NTP in a transgenic non-human animal would result in cell death and depletion of cells in the animal. The specification does not teach one skilled in the art how to use the claimed transgenic non-human animal if overexpression of AD7c-NTP results in death of the transgenic animal.

Furthermore, with respect to Exhibits A-E, the argument is moot because it is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement, e.g. Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997).

Furthermore, with respect to the assertion that the level of transgene expression required for a phenotype will be known to the scientists and clinicians utilizing the non-human transgenic animals. The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:
It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.
In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].
On this record, it is apparent that the specification provides no more than a plan or invitation in view of the art of record exemplifying the unpredictability of predicting a phenotype for those skilled in the art to experiment with level of overexpression so as to provide a transgenic non-human animal for any use as intended by the as-filed specification at the time the invention was made.

See also Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)
("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")
In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for how to use the claimed transgenic animals with no phenotype or how to predict a desired phenotype, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the assertion in the specification to the claimed invention. Therefore, the as-filed specification is not enabled for the claimed invention.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER